IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA	*	
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	*	
v.	*	**CRIMINAL NO. PJM-14-0362**
	*	
SILVIU ZISCOVICI, M.D.,	*	
a/k/a "Dr. Z"	*	
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DEFENDANT DR. SILVIU ZISCOVICI'S
MOTION TO EXCLUDE PURPORTED EXPERT TESTIMONY

Defendant Dr. Silviu Ziscovici respectfully moves the Court to exclude the Government's proffered expert testimony of Dr. Michael A. Ashburn, Dr. Laura Labay, Dr. Steven C. Cogswell, Dr. John C. Neff, and Shirley Nzo-Nguty pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and its progeny and Federal Rule of Evidence 702.

BACKGROUND

Dr. Ziscovici is a physician who was first licensed to practice in Maryland in April 1995. He opened a family practice in 1996. Beginning in late 2009, the U.S. Drug Enforcement Administration ("DEA") initiated a multi-agency investigation of Dr. Ziscovici's practice, particularly focusing on his treatment of patients who were prescribed controlled substances for pain. The government executed a search and seizure warrant at Dr. Ziscovici's residence and medical office in March 2010, and the Maryland Board of Physicians summarily suspended Dr. Ziscovici's license in December 2010. In July 2014, the Government initiated this action against Dr. Ziscovici, alleging that he unlawfully distributed controlled substances between July 28, 2009 and June 22, 2010. (*See* ECF No. 1.)

In September 2015, the Government served its supplemental notice of intent to use expert testimony ("Notice") (Ex. 1).[1] The Notice disclosed that the Government would seek to rely on the testimony of four physicians and one pharmacist. One of the physicians, Dr. Michael A. Ashburn, [redacted] (*See* Ex. 2, at 2; Ex. 3.) The three other physicians (Drs. Labay, Cogswell, and Neff) are pathologists and/or toxicologists who analyzed the death of Ms. Karen Holbrook, a one-time patient of Dr. Ziscovici. Finally, the Government's fifth purported expert is a pharmacist (Ms. Nzo-Nguty) who, on some occasions, according to the Notice, refused to fill Dr. Ziscovici's prescriptions.

For the reasons set out more fully below, the Court should exclude the testimony of Dr. Ashburn, Dr. Labay, Dr. Cogswell, Dr. Neff, and Ms. Nzo-Nguty because their testimony is irrelevant, unreliable, and more prejudicial than probative.

LEGAL STANDARD

Pursuant to Rule 702 and Supreme Court case law, this Court has a duty to act as gatekeeper to ensure that expert testimony presented to the jury is reliable and relevant. *See Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579, 589 (1993); *United States v. Katsipis*, 598 Fed. App'x 162, 164 (4th Cir. 2015). Expert testimony is admissible only if: (a) "the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid 702; *see also Daubert*, 509 U.S. at 589. "The proponent of [expert] testimony

[1] All exhibits referenced herein are to the Declaration of Brett C. Reynolds, attached hereto as Exhibit A.

must establish its admissibility by a preponderance of proof." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

Reliability is a "touchstone for admissibility under *Daubert*." *United States v. Crisp*, 324 F.3d 261, 268 (4th Cir. 2003). "Because expert witnesses have the potential to be both powerful and quite misleading, it is crucial that the district court conduct a careful analysis into the reliability of the expert's proposed opinion." *United States v. Fultz*, 591 Fed. App'x 226, 227 (4th Cir. 2015) (internal quotation marks omitted). Reliable expert testimony is "based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods." *Cooper*, 259 F.3d at 200.

In addition, under Rule 702, expert testimony is only admissible if it is "relevant to the task at hand." *Daubert*, 509 U.S. 588. The Court must determine whether the expert testimony "will assist in the determination of a fact in issue." *Zellers v. NexTech Ne., LLC*, 533 Fed. App'x 192, 196 (4th Cir. 2013). There must be a "valid scientific connection to the pertinent inquiry." *Daubert*, 509 U.S. at 591.

Finally, even if it satisfies Rule 702, expert testimony may be precluded as irrelevant under Rule 402, or else under Rule 403 "if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, [or] misleading the jury." Fed. R. Evid. 403; *see also Dixon v. CSX Transp., Inc.*, 990 F.2d 1440, 1452 (4th Cir. 1993). The Supreme Court has cautioned about the heightened risk of unfair prejudice posed by expert testimony and has stated that, because of this risk, "the judge in weighing possible prejudice against probative force under Rule 403 of the present rules exercises more control over experts than over lay witnesses." *Daubert*, 509 U.S. at 595.

ARGUMENT

I. THE COURT SHOULD EXCLUDE THE TESTIMONY OF DR. MICHAEL A. ASHBURN BECAUSE IT IS UNRELIABLE AND IRRELEVANT.

Dr. Ashburn is a professor of Anesthesiology and Critical Care at the Hospital of the University of Pennsylvania School of Medicine, whom the Government will seek to qualify as an expert in the field of pain management. (Ex. 1, at 1.) According to the Notice, Dr. Ashburn will opine "that the Defendant's actions relating to the charged counts in the Indictment were not for legitimate medical purposes in the usual course of his professional medical practice and/or were beyond the bounds of medical practice." (*Id.* at 2.) He will also testify "as to the standard of care required for pain management practitioners" and "that the Defendant's actions fell below the standard of medical practice." (*Id.*) Dr. Ashburn will provide further testimony about "the Controlled Substances Act and how it guides pain management practitioners in their treatment of patients," "the classification of different prescription medications into schedules under the Controlled Substances Act," "how narcotics are used with or without other modalities of treatment in the normal context of pain management practice," and "other medical or pain management issues that may arise in this case." (*Id.* at 2-3.) For all of these opinions, the Government expects Dr. Ashburn to rely on "his training and experience and on pain management practice guidelines" as well as on "his review of the Defendant's records and prescription practices for specific patients referenced in the Indictment." (*Id.* at 1-2.)

In addition to its Notice, the Government provided a report by Dr. Ashburn based on his review of [redacted]. Therein, Dr. Ashburn opined that there was [redacted]

[redacted] (Ex. 4, at 80.) Dr. Ashburn's expected testimony, however, lacks the relevance and reliability required under Rule 702 and the *Daubert* progeny and, thus, should be excluded.

A. Dr. Ashburn's Opinions Are Derived from Inapplicable Standards.

At the outset of his report, Dr. Ashburn describes the [redacted] he utilized in coming to his conclusions. In addition to [redacted] (Ex. 4, at 4-7.) His use of both sets of materials renders his opinions therefrom unreliable.

First, the [redacted] is inapplicable to Dr. Ziscovici's issuance of controlled substances prescriptions three to four years prior to its creation — in 2009-2010. *See Gen'l Elec. Co. v. Joiner*, 522 U.S. 136, 144-46 (1997) (affirming lower court's exclusion of expert because the studies he relied upon were "far-removed" from "the facts presented in this litigation"). Oblivious to this logical disconnect, Dr. Ashburn relies on the "standards" he gleans from [redacted]. (*See* Ex. 4, at 4-6.) Nowhere does he distinguish among the [redacted] he is applying to reach his conclusions; and, thus, each of his conclusions stem from

"standards" inapplicable to the action at hand. (*See Garlinger v. Hardee's Food Sys., Inc.*, 16 Fed. App'x 232, at 236 (4th Cir. 2001) (excluding expert testimony on effect of hot liquids on human skin where pertinent inquiry was whether temperature at which coffee was served was reasonable, explaining, "although [the expert's] testimony . . . may have scientific validity in some contexts, it does not 'fit' this case."); *see also* Ex. 4, at 9, 11, 12, 14, 15, 16, 18, 20, 22, 23, 28, 30, 32, 33, 35, 36, 38, 41, 43, 45, 48, 50, 59, 60, 64, 65, 66, 68, 69, 71, 73, 76, 79 (stating, [redacted] (emphasis added)).)

Second, Dr. Ashburn does not identify whether the [redacted] upon which he relies was generally-accepted in the medical community at the time of Dr. Ziscovici's charged conduct — much less whether that [redacted] was even in existence at that time. Given this lack of information, the Court simply cannot hold that Dr. Ashburn's testimony "is based on sufficient facts or data" and "is the product of reliable principles and methods." Fed. R. Evid. 702(b)-(c).

Moreover, [redacted] are distinct from the criminal standard of liability that applies to this action. The Fourth Circuit has made clear that "there are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice." *United States v. Boccone*, 556 Fed. App'x 215, 228 (4th Cir. 2014). To find a physician liable for violating 21 U.S.C. § 841(a)(1), the Government must show, beyond a reasonable doubt, that "the controlled substance[s] w[ere] not prescribed [] 'for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." *United States v. Orta-Rosario*, 469 Fed. App'x 140, 143 (4th Cir. 2012) (internal citation omitted). This standard is not met by showing that the physician is "bad or negligent," but only by

showing that "he ceases to be a physician at all." *United States v. Feingold*, 454 F.3d 1001, 1011 (9th Cir. 2006); *accord Gonzalez v. Oregon*, 546 U.S. 243, 270 (2006) (stating that Controlled Substances Act bars physicians from issuing prescriptions "for illicit drug dealing and trafficking as conventionally understood"). In contrast, the sources upon which Dr. Ashburn relies are [redacted] These are not testable standards against which to judge whether a physician was acting as a common drug dealer. Despite this inapplicability, Dr. Ashburn concludes after his review of [redacted] (*See* Ex. 4, at 9, 11, 12, 14, 15, 16, 18, 20, 22, 23, 28, 30, 32, 33, 35, 36, 38, 41, 43, 45, 48, 50, 59, 60, 64, 65, 66, 68, 69, 71, 73, 76, 79 (emphasis added).) Because Dr. Ashburn utilized inapplicable standards to reach his opinions, the Court should exclude Dr. Ashburn's testimony.

B. Dr. Ashburn's Opinions Are Untethered to the Standards Which He Seeks to Apply.

Even assuming *arguendo* that the "standards" applied by Dr. Ashburn were relevant and reliable, his opinions should nevertheless be excluded because they are no more than *ipse dixit*, that is conclusory statements untethered to the "standards" and experience upon which he purports to rely. Following his [redacted] These conclusions, however, are not preceded

by an application of the purported "standards" to the material reviewed, or even by an application of Dr. Ashburn's experience to his [redacted] Instead, [redacted] [2] without explanation.

For example, the majority of [redacted]

[redacted]

(*See generally* Ex. 4.) Such conclusions do not, for example, cite to the particular "standards" that were allegedly violated, or the specific trainings or experiences that Dr. Ashburn is bringing to bear to reach the conclusions. Neither does Dr. Ashburn, for example, attempt to define his use of ambiguous terms or explain their origin. Thus, Dr. Ashburn's report is missing a pivotal step — a reasoned explanation of the sources relied upon for each conclusion and of how those sources led to such conclusions.

[2] Inexplicably, conclusions were not provided for [redacted]. *See* Ex. 4, at 10, 70. [redacted]. *See id.* at 12 [redacted] 34 [redacted] 73 [redacted]

Rule 702 codifies what is required to adequately support an expert's opinions. It states that an expert witness must provide testimony that "is the product of reliable principles and methods" and must "reliably appl[y] the principles and methods to the facts of the case." Fed. R. Evid. 702(d). The advisory committee notes to the 2000 amendment to Rule 702 explain that, "[i]f the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply 'taking the expert's word for it.'" (Fed. R. Evid. 702 advisory committee's note (2000).) Indeed, even a generous reading Dr. Ashburn's report does not transform any of his statements to an *application* of his experiences or of his gleaned "standards" [redacted]

A similar concern is present with regard to Dr. Ashburn's proposed testimony regarding the Controlled Substances Act ("CSA"). The Notice states that Dr. Ashburn will testify about "how [the CSA] guides pain management practitioners in their treatment of patients." Yet, the Notice does not outline what methodology Dr. Ashburn would apply to determine how pain management practitioners, other than Dr. Ashburn, are guided by the CSA. For example, the Notice does not state that Dr. Ashburn has undertaken surveys or run focus groups of other pain management practitioners, let alone communicated with other pain management practitioners regarding this topic. Neither does it state that Dr. Ashburn has conducted a literature search on this topic. It is improper, under *Daubert*, to make an empirical claim about the behavior of physicians — that is, how they are guided by the CSA — without relying on related empirical evidence to support that claim. *See Daubert*, 509 U.S. at 590 (stating that Rule 702 requires "more than subjective belief or unsupported speculation"); *see also Minasian v.*

Standard Chartered Bank, PLC, 109 F.3d 1212, 1216 (7th Cir. 1997) (warning "how vital it is that judges not be deceived by the assertions of experts who offer credentials rather than analysis").

But, perhaps the most egregious examples of Dr. Ashburn's conclusory and unfounded opinions are where he [redacted] (*See* Ex. 4, at 38, 68.) Like Dr. Ashburn's other conclusions, these statements are not preceded by the application of sources or his experiences to the facts. In fact, none of the "standards" upon which Dr. Ashburn seeks to rely speaks to the determination of [redacted] and Dr. Ashburn's experiences do not, on their face, lend themselves to making such a determination. Dr. Ashburn appears not to have conducted any scientific tests to determine [redacted]. Indeed, the fact that the Government itself retained three other purported experts to opine as to [redacted] underscores Dr. Ashburn's inability (and thus lack of application of methodology to conclusion) to opine regarding [redacted] *Cf., e.g., Bickel v. Pfizer, Inc.*, 431 F. Supp. 2d 918, 922 (N.D. Ind. 2006) (excluding expert physician's testimony that drug manufactured by defendant "most likely caused" injury to plaintiff where physician "did not conduct any scientific tests, experiments, or clinical studies to bolster her theory . . . nor did she produce or rely upon any studies to verify her conclusions. Such insulation of her theory from the dispassionate crucible deeply, if not fatally, compromises her testimony's reliability.").

Because Dr. Ashburn's opinions are nothing more than conclusory assertions ungrounded in reliable methodologies, his opinions do not pass muster and should be excluded.

C. Dr. Ashburn's Experience-Based Methodology is Error-Prone.

Dr. Ashburn's opinions should also be excluded because [redacted] that distinguished panels of pain experts have deemed "unfounded," "factually wrong," and

"junk science." (Ex. 7; Ex. 8; Ex. 9, at 5.) Pursuant to *Kumho Tire Company, Ltd. v. Carmichael*, 526 U.S. 137 (1999), it is appropriate to "draw a conclusion from a set of observations based on extensive and specialized experience." *Id.* at 156. However, in performing its gatekeeping responsibility, it is appropriate for the Court to test "how often an [] expert's experience-based methodology has produced erroneous results." *Id.* at 151. The prior cries of error with regard to Dr. Ashburn's previously-articulated opinions — [redacted] — thus are eminently relevant to the Court's *Daubert* analysis.

In 2004, six past presidents of the American Pain Society ("APS") wrote to defense counsel in another unlawful distribution of controlled substances action to express their "deep[] concern[s]" about the "serious misrepresentations in the testimony provided by the government's expert, Dr. Michael Ashburn." (Ex. 8.) They stated that their review of Dr. Ashburn's testimony in that case revealed that Dr. Ashburn's testimony "serious[ly] misstate[d] [the] consensus in the field." (*Id.*) They specifically outlined five "points of sharp disagreement" between Dr. Ashburn's testimony and the consensus in the field, which were Dr. Ashburn's statements that (a) "the use of 'high-dose' opioid therapy is an indication of drug abuse in populations with chronic non-cancer pain;" (b) "morphine at a dose of 195 mg/day constitutes a high dose;" (c) "opioid treatment of a patient with a known addiction is medically wrong and worsens the addiction;" (d) "high dose opioids produce hyperalgesia (increased pain) and therefore may worsen the clinical pain problem;" and (e) "high dose opioids may compromise the immune system." (*Id.*) Later, the Association of American Physicians and Surgeons ("AAPS") wrote to the judge presiding over the same case and expressed agreement with those past presidents of APS. AAPS explained that Dr. Ashburn's "false expert testimony was egregious and far worse than routine disagreements among medical professionals. [Rather, t]he errors identified . . . were shocking,

highly material, and profoundly unjust." (Ex. 7.) In a subsequent *amicus* brief to the Fourth Circuit, AAPS called Dr. Ashburn's same conclusions "junk science." (Ex. 9, at 5.)[3]

Despite these admonitions by preeminent leaders in the pain management field, Dr. Ashburn [redacted]. (*See* Ex. 4, at 7 (stating that [redacted]); Ex. 1, at 2 (stating that Dr. Ashburn will testify that "large dosages" of controlled substances "indicat[e] that the patients were illegally using or diverting the drugs").) The statements have been denounced as "absurd" (Ex. 8) and the Court should thus exclude them as the production of unreliable experience-based methodology. *See Kumho*, 526 U.S. at 151.

D. Dr. Ashburn's Opinions Based on In-Office Drug Tests are Unreliable.

Equally problematic is Dr. Ashburn's intended reliance on "failed drug tests" to "indicat[e] that the patients were illegally using or diverting the drugs." (*See* Ex. 1, at 2.) This is because, at the time Dr. Ziscovici was administering the drug tests, it was generally accepted in the medical community that drug tests of this type were unreliable. *See, e.g.*, Ex. 10, at 387 (explaining that urine drug screens are subject to false-positive results and that testing for selected drug classes, such as opiates and benzodiazepines, are also subject to "clinically important false negatives"); Ex. 11, at 1639 (stating that non-laboratory tests for drug abuse should be "used with caution" because they "provide only initial screening data and may yield false-positive or -negative results"); Ex. 12, at 18 ("Final clinical decisions on drug abuse or non-compliance should not solely be made by on-site testing . . . since they do not technologically muster to the quality of commercial laboratories."); Ex. 13, at 15

[3] The Fourth Circuit did not consider the reliability of Dr. Ashburn's testimony because it was not a point of appeal.

(stating that urine drug test "cannot indicate the amount of drug taken, when the last dose was administered or the source of that drug"); Ex. 14, at 1800 (explaining that point-of-care urine drug tests are "susceptible to cross-reactions, resulting in false-positive results"). Pursuant to *Daubert*, opinions based on unreliable results are themselves unreliable and, thus, should be excluded. *See Kumho*, 526 U.S., at 151 (expert opinion not reliable "where the discipline itself lacks reliability, as, for example, do theories grounded in any so-called generally accepted principles of astrology or necromancy"); Fed. R. Evid. 702 advisory committee's note ("Whether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give is an additional factor for considering the reliability of an expert's testimony under *Daubert*.").

E. Dr. Ashburn's Opinions Are Based on Unreliable Samples.

Finally, Dr. Ashburn's review of [redacted], selected with no discernible methodology, renders his opinions based on that review unreliable. (*See generally* Ex. 4.) Courts, including those in this Circuit, have routinely excluded expert opinions based on improper sample size or selection. *See, e.g.*, *Edwards v. Ethicon, Inc.*, 2014 WL 3361923, at *23 (S.D. W. Va. July 8, 2014) (excluding expert's opinions because he "has given no explanation as to whether his is a representative sample size or how he chose the particular [sample] analyzed" (internal alterations and quotation marks omitted)); *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, 2014 WL 186872, at *8 (S.D. W. Va. Jan. 15, 2014) (excluding expert's testimony because expert did not articulate method for selecting sample); *Loeffel Steel Prods., Inc. v. Delta Brands, Inc.*, 387 F. Supp. 2d 794, 811-17 (N.D. Ill. 2005) (excluding proffered expert's testimony on lost profits damages because expert failed to rely on comparable samples, making resulting opinion "manifestly unreliable" and unable to "logically advance a material aspect of the proposing party's case" (internal quotation marks and alterations omitted)); *cf.*

Watkins v. Cook Inc., 2015 WL 1395773, at *16 (S.D. W. Va. Mar. 25, 2015) (reserving judgment on plaintiff's *Daubert* motion pending subsequent hearing, but stating that "an unscientific sample of the expert's [own] patients is not an adequate foundation to suggest reliability under *Daubert*" for purposes of expert's causation opinion).

Here, the Government appears to have selected [redacted] for Dr. Ashburn to review, out of the more than 3,000 patients (and nearly 800 pain patients) that Dr. Ziscovici has treated during his tenure as a physician. (*See* Ex. 4, at 1, 4 (Ashburn stating that [redacted]); Ex. A, at ¶ 27.) The selection of [redacted] of Dr. Ziscovici's practice. This is especially troubling because Dr. Ashburn draws sweeping conclusions from his review of that sample. For example, Dr. Ashburn opines, without any language limiting his statement to the documents he reviewed, that [redacted] (Ex. 4, at 7 (emphasis added).) He also makes the expansive statement that there was [redacted], based only on the sample that he reviewed. (*Id.* at 80 (emphasis added).) Such broad-based conclusions are improperly drawn from the Government's limited sample. *Cf. United States v. Mikos*, 2003 WL 22922197, at *4 (N.D. Ill. Dec. 9, 2003) (finding that FBI database of bullet samples could not serve as basis for expert testimony because size of database was "extremely small to be used to reliably extrapolate principles as to the total bullet population").

Moreover, the selection of [redacted] is inherently suspect as it was made by a party to the action using no articulated methodology. *See In re Ethicon*, 2014 WL 186872, at *8 ("Again, Dr. Klinge does not explain how he selected these 22 particular samples. There are no

assurances that Dr. Klinge — or plaintiffs' counsel — did not opportunistically choose samples while ignoring others that might have weakened or disproved his theories. In short, there are no indications that Dr. Klinge's analyses of the mesh implants were controlled for error or bias."); *Yapp v. Union Pac. R.R. Co.*, 301 F. Supp. 2d 1030, 1037 (E.D. Mo. 2004) (stating that "the heavy involvement of defense counsel in the design and conduct of a survey used to guide expert statistical analyses indicates a lack of independence and thus a lack of scientific validity"); *cf. Coleman v. Union Carbide Corp.*, 2013 WL 5461855, at *36 (S.D. W. Va. Sept. 30, 2013) (stating, where plaintiffs' counsel selected the number of samples to examine and the samples themselves, that such "sampling and testing process is not indicative of the disciplined use of the scientific method. . . . All the more troubling is that [the expert] did not scrutinize for selection bias the testing sites chosen by counsel.").

The Court should bar Dr. Ashburn from testifying based on an inadequate and unprincipled sample. In the alternative, the Court should limit Dr. Ashburn's testimony to preclude him from purporting to draw broad conclusions about Dr. Ziscovici's practice based on that sample. *See Menasha Corp. v. News Am. Mktg. In-Store Inc.*, 238 F. Supp. 2d 1024, 1030 (N.D. Ill. 2003) (excluding portions of expert's testimony that relied on survey found to be unreliable because, in part, the survey sample did not "accurately represent[] the target population" and "procedures [were not] taken to reduce the likelihood of a biased sample").

II. THE COURT SHOULD EXCLUDE THE TESTIMONY OF DRS. LABAY AND COGSWELL BECAUSE THE METHODOLOGY UPON WHICH THEY RELY IS UNRELIABLE.

Dr. Laura Labay is a toxicologist, and Dr. Steven Cogswell is a forensic pathologist. The Government intends to offer the testimony of Dr. Labay to describe "the toxicology tests performed on samples taken from [the] body" of one-time patient of Dr. Ziscovici, Ms. Karen Holbrook, and "the

levels and types of drugs found in Ms. Holbrook's body." (Ex. 1, at 4.) The Government intends to offer the testimony of Dr. Cogswell to opine "on the cause of death for [Ms.] Holbrook . . . based, at least in part, on the toxicology report prepared by 'NMS Labs' regarding the level and combination of drugs found in Ms. Holbrook's body at the time of her death." (*Id.*) Implicit in each of these noticed topics is the reliance of both Drs. Labay and Cogswell on the results of Dr. Labay's analysis of Ms. Holbrook's post-mortem blood levels. However, such testimony should be excluded because it does not satisfy the reliability requirements of Rule 702 and the *Daubert* progeny.

The use of post-mortem blood levels is not a reliable scientific methodology to determine the cause of death. (*See, e.g.*, Ex. 15, at 12 ("[P]ostmortem blood concentrations of methadone do not appear to reliably distinguish between individuals who have died from methadone toxicity and those in whom the presence of methadone is purely coincidental.").) This is because, after death, drugs redistribute throughout the body through a phenomenon called post-mortem redistribution ("PMR"), or the "movement of drugs and other chemical poisons between tissues, organs, and body fluids." (Ex. 16, at 282.) Because of this migration, "postmortem samples do not necessarily reflect the blood concentrations at the time of death." (Ex. 17, at 533.) Thus, extrapolation therefrom to determine pre-death (or ante-mortem) drug toxicity is "dangerous," if not impossible. (Ex. 16, at 284; *see also id.* at 282 ("There is a lack of evidence that such an extrapolation [of ante-mortem drug levels from postmortem samples] is possible."). This is especially true with regard to tests for methadone toxicity, as methadone "increase[s] significantly after death." (Ex. 18, at 5.) There is no indication that any of these proffered witnesses addressed the issue of PMR, let alone did so in a scientifically valid and reliable way. And, the unreliability of post-mortem methadone blood levels is further compounded

when blood samples are collected from the heart (*see* Ex. 19, at 245),[4] or more than four hours after death (*see* Ex. 16, at 283).[5]

Because of the unreliability of postmortem blood analysis to determine ante-mortem drug levels in the blood, courts across the country have excluded testimony on the subject. *See, e.g., Manous v. Mylan Pharms. Inc.*, 982 F. Supp. 2d 1277, 1280-81 (W.D. Okl. 2013) (excluding doctor's testimony, which appeared to "be the product of assuming that because [the decedent's] postmortem blood level was 28.1 ng/ml, and because he is aware that this concentration is high, that her death was the result of Fentanyl toxicity" in part because such analysis did not address PMR); *In re Digitek Prod. Liab. Litig.*, 821 F. Supp. 2d 822, 839-41 (S.D. W. Va. 2011) (excluding expert testimony, explaining that the "key problem" is that expert's opinions relied on postmortem blood levels and "did not adequately account for the [post-mortem redistribution of blood] effect," which "would elevate [the decedent's] postmortem digoxin levels, making the 3.6 level totally unreliable for purposes of extrapolating to his pre-death mark."); *Battle v. Gold Kist, Inc.*, 77 Fed. R. Evid. Serv. 445, at *7-8 (M.D. Fla. 2008) (excluding expert opinion based on certain post-mortem blood levels because, among other things, literature "raises serious questions about the reliability of post-mortem measurements of drug concentration in blood" and "[r]eliability cannot be established by the mere *ipse dixit* of an expert").

Simply put, "[t]here is no reliable or obvious connection between concentrations [of drugs in the blood] measured in life and subsequent to death. Consequently, concentrations measured

[4] Here, it is not apparent from where the blood sample was collected. *See* Ex. 24 (noting [redacted]).

[5] Here, the blood sample appears to have been collected [redacted]); Ex. 25 (noting that [redacted]).

after death cannot generally be interpreted to yield concentrations before death." (Ex. 20, at 440.) Given the unreliability of their methodology, the testimony and opinions of Drs. Labay and Cogswell should be excluded. *See* Fed. R. Evid. 702 (expert testimony admissible only if it is "based upon sufficient facts or data" and is "the product of reliable principles and methods"); *see also Joiner*, 522 U.S. at 146-47 (holding that a District Court did not abuse its discretion to exclude expert testimony where it concluded that the scientific evidence upon which it was based was insufficient to support the expert's opinion).

III. THE COURT SHOULD EXCLUDE THE TESTIMONY OF DR. JOHN C. NEFF BECAUSE HE IS UNQUALIFIED TO OPINE AS AN EXPERT ON THE NOTICED SUBJECT.

The Government seeks to qualify a third expert — Dr. John C. Neff — to opine on the cause of death for Ms. Holbrook based on the autopsy he conducted of Ms. Holbrook. (*See* Ex. 1, at 3.) To so opine, the Government "expects to qualify Dr. Neff as an expert in forensic pathology." (*Id.*) However, Dr. Neff's qualifications do not support the Government's characterization of him or his causation opinion. First, Dr. Neff's curriculum vitae ("CV") reveals that he is board certified in anatomical and clinical pathology — not forensic pathology. (*See* Ex. 21, at 1.) His CV does not indicate that he has any training or certifications in forensic pathology, and nothing therein relates to forensic pathology in any way. (*See id.* at 1-13; *see also* Ex. 22 (listing "clinical focus" as "surgical pathology, renal pathology, immunopathology").) Next, and perhaps even more troubling, Dr. Cogswell, the actual forensic pathologist the Government seeks to qualify, earlier explained to the Government that [redacted] (Ex. 23, at ZISCOVICI_7459.) Indeed, because Dr. Neff lacked the qualifications of medical examiners generally,

he only [redacted] (*Id.*) Dr. Cogswell further informed the Government that, as a [redacted] Dr. Neff was [redacted] (*Id.* at ZISCOVICI_7460.) Accordingly, Dr. Cogswell [redacted]. (*Id.* at ZISCOVICI_7459.)

Because Dr. Neff is not a forensic pathologist and otherwise lacks the expertise to make causation determinations that medical examiners customarily make, he is not qualified to opine regarding the cause of death of Ms. Holbrook. His testimony should be excluded pursuant to *Daubert* and Federal Rules of Evidence 702 and 403. *See* Fed. R. Evid. 702(a) (requiring that an "expert's scientific, technical, or other specialized knowledge will help the trier of fact to . . . determine a fact in issue"); Fed. R. Evid. 403; *Daubert*, 509 U.S. at 595 (acknowledging that expert testimony can be both powerful and misleading, such that the judge "should exercise more control over experts than over lay witnesses"); *see also Rasmussen v. City of N.Y.*, 2011 WL 744522, at *3 (E.D.N.Y. Feb. 23, 2011) (holding that expert was unqualified to testify about cause of plaintiffs' injury because he admitted that "he was not a forensic pathologist").

IV. THE COURT SHOULD EXCLUDE THE TESTIMONY OF SHIRLEY NZO-NGUTY BECAUSE IT IS IRRELEVANT, UNRELIABLE, AND WILL CONFUSE AND MISLEAD THE JURY.

Ms. Shirley Nzo-Nguty is a pharmacist, who the government seeks to qualify as "an expert concerning the proper dispensation of controlled substances as a pharmacist." (Ex. 1, at 5.) As described in the Notice, Ms. Nzo-Nguty will testify regarding two topics: (1) the proper dispensation of controlled substances as a pharmacist to patients who may show signs of drug dependence and abuse; and (2) her familiarity with Dr. Ziscovici and occasions during which she refused to fill Dr. Ziscovici's

prescriptions. Ms. Nzo-Nguty's expected testimony lacks the relevance and reliability required under Rule 702 and the *Daubert* progeny and, thus, should be excluded.

A. Ms. Nzo-Nguty's Testimony As "An Expert Concerning the Proper Dispensation of Controlled Substances as a Pharmacist" Is Not Relevant to Dr. Ziscovici's Conduct.

Ms. Nzo-Nguty's testimony as an "expert concerning the proper dispensation of controlled substances *as a pharmacist*" (Ex. 1, at 5 (emphasis added)), is not "relevant to the task at hand." *Daubert*, 509 U.S. 588. Here, the relevant inquiry is whether Dr. Ziscovici, *as a physician*, wrote prescriptions for controlled substances that "were not for legitimate medical purposes in the usual course of his professional medical practice." *See United States v. Hurwitz*, 459 F.3d 463, 475 (4th Cir. 2006). Testimony about how a pharmacist should dispense controlled substances after they have been prescribed by a physician is entirely distinct from, and does not have a "valid scientific connection to[,] the pertinent inquiry." *See Daubert*, 509 U.S. at 591. The prescribing physician and dispensing pharmacist have different types of medical training, different levels of interactions with a patient, and different professional guidelines and practices. *See, e.g., United States v. Mukherjee*, 289 Fed. App'x 107, 110 (6th Cir. 2008) (finding that the district court did not abuse its discretion in refusing to permit a pharmacist to testify about whether a physician's prescriptions constituted appropriate medical practice because the proposed expert was "a pharmacist who could not issue prescriptions . . . not a physician" and his "skills and qualifications were in analyzing and filling prescriptions" not "determin[ing] what treatment (including appropriate medication) would be appropriate for a particular condition or patient"); *United States v. Caroni*, 2011 WL 4102331 (N.D. Fla. Sept. 13, 2011) (explaining that while proposed expert was an expert in pharmacology, "he is not a medical doctor and thus is not qualified to testify whether a given prescription was written for a legitimate medical purpose within the usual course of professional medical practice").

B. Ms. Nzo-Nguty's Proposed Expert Testimony Is Unreliable.

According to the Notice, Ms. Nzo-Nguty "will testify regarding the proper dispensation of controlled substances as a pharmacist" to "patients who may show signs of drug dependence and abuse" and regarding occasions on which she "refused to fill Dr. Ziscovici's prescriptions." (Ex. 1, at 5.) The Notice suggests that Ms. Nzo-Nguty's testimony will be based on her experience as a "licensed pharmacist since 1997."

The Notice raises doubts about the reliability of Ms. Nzo-Nguty's proposed testimony. While an expert's opinions may be based solely on his/her experience if that experience renders that person a qualified expert (*see* Fed. R. Evid. 702), the reliability of an expert whose opinion rests on experience requires examination by the court. In measuring reliability of an expert's opinion resting on experience, Rule 702 requires that the expert "explain how [her] experience leads to the conclusions reached, why [her] experience is a sufficient basis for the opinion, and how [her] experience is reliably applied to the facts." *United States v. Wilson*, 484 F.3d 267, 274 (4th Cir. 2007) (quotation marks omitted).

The Government has not shown, by its Notice, that Ms. Nzo-Nguty's methodology or guiding principles are sound and whether her opinions and inferences are "based on scientific, technical, or other specialized knowledge" as opposed to "belief or speculation." *See Cooper*, 259 F.3d at 200. For example, it is unclear how, if at all, Ms. Nzo-Nguty's experience lends itself to determining when "patients [are] . . . show[ing] signs of drug dependence or abuse." (Ex. 1, at 5.) Additionally, it is not clear what methodology Ms. Nzo-Nguty used in "refusing to fill Dr. Ziscovici's prescriptions," if she employed any methodology at all, and how subjective or controversial any such methodology was. *See* Fed. R. Evid. 702, advisory comm. notes, 200 amend. ("The more subjective and controversial the

expert's inquiry, the more likely the testimony should be excluded as unreliable); *see also United States v. Garcia*, 752 F.3d 382, 395 (4th Cir. 2014) (explaining that there was a "fundamental flaw" in an expert's testimony because of the "lack of foundations laid for each interpretation testified to" and that the flaw was so severe that the Court was "compelled to conclude that the record fails to demonstrate the requisite reliability in [the expert's] execution of her claimed methodology"); *United States v. Johnson*, 617 F.3d 286, 294-95 (4th Cir. 2013) (explaining that, although a law enforcement officer indicated that he had expertise to testify regarding drug jargon, "he provided virtually no methodology or guiding principles that would enable him to decode the wiretapped phone calls" at issue).

C. Ms. Nzo-Nguty's Proposed Expert Testimony and Fact Testimony Will Mislead and Confuse the Jury.

To the extent that the Government seeks to have Ms. Nzo-Nguty testify regarding her familiarity with Dr. Ziscovici during the time period covered in the Indictment and her non-technical observations of patients seeking to fill prescriptions from Dr. Ziscovici, Ms. Ngo-Nguty will be testifying as a fact witness. As the Fourth Circuit has recognized, "individuals who testify as expert and fact witnesses can cause jury confusion, and such a manner of proceeding is only 'acceptable where the district court took adequate steps . . . to make certain that [the witness'] dual role did not prejudice or confuse the jury.'" *Garcia*, 752 F.3d at 392. Because of Ms. Nzo-Nguty's professional background, her presence on the stand will imbue her entire testimony with an air of expertise; thus, it is nearly impossible for any measures taken by the Court to divide her testimony into expert and non-expert to be "adequate." *Cf. United States v. Haines*, 803 F.3d 713, 730 (5th Cir. 2015) (explaining that when fact witnesses also function as experts for the government, the government "confers upon [them] the aura of special reliability and trustworthiness surrounding expert testimony," which "creates a risk of prejudice" and gives the witness "unmerited credibility when testifying about factual matters from first-hand

knowledge" (quoting *United States v. Dukagjini*, 326 F.3d 45, 53 (2d Cir. 2002)). As such, Ms. Nzo-Nguty's expert testimony should be excluded because its probative value is substantially outweighed by the danger of misleading the jury. *See Daubert*, 509 U.S. at 595 ("[T]he judge in weighing possible prejudice against probative force under Rule 403 of the present rules exercises more control over experts than over lay witnesses.").

CONCLUSION

For the aforementioned reasons, the Court should exclude the testimony of Dr. Ashburn, Dr. Labay, Dr. Cogswell, Dr. Neff, and Ms. Nzo-Nguty. In the alternative, the Court should schedule a hearing to test the reliability and relevance of the proffered testimony from the Government's proffered experts.

Dated: May 6, 2016

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I electronically filed the foregoing document with the Clerk of the Court using CM/ECF on this 6th day of May, 2016. I also certify that the foregoing document is being served this day on all counsel of record registered to receive electronic Notices of Electronic Filing generated by CM/ECF.

By: /s/ Brett C. Reynolds
Brett C. Reynolds
Admitted Pro Hac Vice